

AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF
1,4-DIOXANE
AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) 1907/2006¹

Adopted on 15 June 2021

This agreement concerns

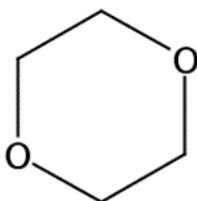
Substance name: 1,4-dioxane

EC number: 204-661-8

CAS number: 123-91-4

Molecular formula: C₄H₈O₂

Structural formula:



¹Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Germany presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (2 March 2021) on identification of *1,4-dioxane* (EC No. 204-661-8) as a substance of very high concern due to its properties for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

The Annex XV dossier was circulated to Member States on 10 March 2021 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 24 May 2021 and discussed in the meeting on 14-17 June 2021 of the Member State Committee.

Agreement of the Member State Committee in accordance with Article 59(8):

1,4-dioxane is identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category 1B.

1,4-dioxane is identified as a substance meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because it is a substance for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

Carcinogenic - Article 57 (a)

1,4-Dioxane is covered by index number 603-024-00-5 of Regulation (EC) No 1272/2008. Pursuant to Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 1,4-dioxane will be classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer")².

Therefore, this classification of the substance shows that it meets the criteria for classification in the hazard class:

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH

Equivalent level of concern - Article 57(f):

1,4-Dioxane is identified as substance of very high concern according to Article 57(f) of regulation 1907/2006 (REACH) due to scientific evidence of probable serious effects to the environment and human health (man via the environment). The scientific evidence gives rise to an equivalent level of concern to substances covered by Article 57 (a) to (e).

Intrinsic properties

Abiotic degradation of 1,4-dioxane by hydrolysis and phototransformation in air and water is regarded as negligible. Based on the weight of evidence, the degradability of 1,4-dioxane is considered to be relatively low in soils under relevant environmental conditions. Degradation of 1,4-dioxane was investigated in surface water according to OECD TG 309, showing no degradation of the substance.

² Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the 17th ATP to CLP). Pursuant to the second paragraph of Article 2 of this Regulation this new harmonised classification applies from 17 December 2022. However, pursuant to the third paragraph of that provision substances and mixtures may already be classified, labelled and packaged in accordance with this classification.

Therefore, the degradation half-life of 1,4-dioxane is obviously higher than 60 days. Considering the data on abiotic and biotic degradation, 1,4-dioxane is considered to fulfil the P/vP criteria (half-life in water >60 days) of REACH Annex XIII.

The substance is completely miscible with water (water solubility used for assessment = 1000 g/L) and has a log K_{oc} of 0.85 indicating a low potential for adsorption on organic matter and clay minerals. These intrinsic substance properties lead to a high mobility in water. Additionally, the intrinsic substance properties indicate that the substance will partition primarily to the water compartment and will undergo environmental distribution via aqueous media, easily reaching groundwaters.

The high water solubility and low sorption potential of 1,4-dioxane make the substance difficult to remove from water as it only has a low potential to adsorb to materials and prefers to remain in the water phase.

Because of 1,4-dioxane's high water solubility, low volatility from water and low potential for adsorption, water will be the dominant transport media in the environment once the substance is released. In combination with its long environmental half-life, there is a potential for widespread contamination of the water environment.

The OECD tool for Long Range Transport Potential (LRTP) predicts a characteristic travel distance (CTD) of 1384 km together with an overall persistence (P_{ov}) of 820 days for 1,4-dioxane. This indicates that 1,4-dioxane is capable of reaching regions far away from the point of initial emission.

The Risk Assessment Committee (RAC) has concluded that 1,4-dioxane fulfils the criteria for classification as carcinogenic Carc. 1B. The classification has been included in the 17th Adaptation to Technical Progress (ATP) to Classification, Labelling and Packaging Regulation (EC) No 1272/2008 (CLP). This classification is of relevance for the assessment of 1,4-dioxane as a substance of very high concern according to Article 57 (f), i.e. under the T-criterion of REACH Annex XIII; Section 1.1.3 b).

Concerns arising from the substance properties

Available information on persistency, mobility and potential for being transported in the water phase over long distances of 1,4-dioxane, gives rise to the concern, that once the substance is released to the environment, the contamination will hardly be reversible. This assumption is supported by a study that analysed the behaviour of 1,4-dioxane during river bank filtration and filtration with activated carbon at the drinking water production facility. The analysis showed that only a small portion of 1,4-dioxane is removed via river bank filtration and filtration with activated carbon. The result indicates, that the substance will not be removed from water by these purification techniques, which are generally applied across Europe. Furthermore, a temporal and spatial distribution from the point of release is to be considered. It needs to be considered that as long as 1,4-dioxane is released to the environment, the environmental levels might increase.

The concern raised by 1,4-dioxane is triggered by individual properties as well as by combination of its properties. Persistence and mobility allow the substance to be dispersed far beyond the sites of release via transport in the water environment. The substance stays in the environment even if releases of the substance have already ceased, as can be concluded from the substance properties and the recurring findings in groundwater samples. The persistency, mobility and toxicity (carcinogenicity) and in addition the irreversibility of the contamination of the

aquatic compartment compromise the quality of drinking water resources.

The substance properties and the irreversibility of the contamination give rise to the concern of increasing exposure to wildlife and man via environment due to contaminated water.

The very high persistency and its mobility result in an increasing pollution of the aquatic environment. 1,4-Dioxane is difficult to remove once emitted to the aquatic environment. 1,4-Dioxane poses a threat to the resources of our drinking water, as due to its persistency and mobility, 1,4-dioxane can bypass river bank filtration and filtration with activated carbon, raising the concern of a continuous exposure of humans via drinking water. Any remediation efforts of contaminated drinking water resources will cause high costs to society. As the substance is very mobile causing a rapid distribution from the point source, remediation measures become even more difficult. Furthermore, 1,4-dioxane is carcinogenic and humans will be exposed to it via consumption and use of drinking water. Consequently, there is societal concern due to the presence of 1,4-dioxane in drinking water that requires immediate action. The environment provides natural drinking water sources, whose integrity needs to be ensured for future generations.

Due to the properties of 1,4-dioxane (persistency, mobility, potential for being transported in the water phase over long distances and carcinogenicity) it is not possible to derive a safe concentration limit for the environment. Monitoring data demonstrate the presence of 1,4-dioxane in surface water, groundwater and even drinking water across the globe. Sources of emission in the vicinity are seldom apparent.

The substance properties like persistency and mobility suggest that the substance might pose a risk on a global scale. It follows that human health and the environment might be affected by 1,4-dioxane on a global scale.

A supporting concern is that although available aquatic studies do not show effects or only at high concentrations, no information is available about other effects to the environment, e.g. on ecotoxic effects to non-model species. **Therefore, the substance properties raise the concern of yet unknown effects on the environment.**

Equivalent level of concern

The level of concern is considered very high in particular due to the combination of the following concern elements:

- Concern for an irreversible and increasing presence in the environment, in particular to the aquatic environment
- Decontamination of 1,4-dioxane from the environment and from drinking water resources is difficult and resource-intensive
- 1,4-Dioxane fulfils the criteria for classification as carcinogenic Carc. 1B and is included in the 17th ATP to CLP
- High societal concern for the presence of 1,4-dioxane in drinking water sources
- Continuous presence in water results in continuous exposure of humans and environment
- Yet unknown environmental and human health effects

Conclusion

Although the carcinogenic properties of 1,4-dioxane alone are sufficient to assess it as a substance of very high concern, it is the combination of its substance properties causing higher concern to the environment and human health (man via the environment). The combined intrinsic properties which demonstrate scientific evidence of probable serious effects to human health and the environment and which give rise to an equivalent level of concern are the following: very high persistence, high mobility in water, potential for being transported in the water phase over long distances, difficulty of remediation and water purification. The observed probable serious effects for human health and the environment are carcinogenicity and yet unknown environmental effects. Together, these elements lead to a very high potential for irreversible effects.

Therefore, it is concluded that the substance *1,4-dioxane* meets the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category 1B, and the criteria of Article 57(f) of REACH, due to its properties for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern to those for other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

Reference:

Support Document (Member State Committee, 15 June 2021)